DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

August 20, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 40

Horst Rechelbacher
Owner
Intelligent Nutrients, Inc.
321 Lincoln Street NE
Minneapolis, Minnesota 55413

Dear Mr. Rechelbacher:

This letter is written in reference to your marketing of the product "Daily Elixir™ First Aid Mixative." The Food and Drug Administration (FDA) collected samples of this product at your 321 Lincoln Street, Minneapolis, MN, location.

An analysis of the "Daily Elixir ™ First Aid Mixative" revealed the actual level of Selenium in the product to be significantly less than listed on the label. The product is labeled to contain 50 mcg or 70% of the Percent Daily Value per 0.07 ounce packet. However, FDA analysis of the two samples of your product found that it contained less than 80% of the amount declared on the label.

This causes your product to be adulterated within the meaning of Section 402(b)(1) of the Federal Food, Drug and Cosmetic Act (the Act) in that a valuable constituent, Selenium, has been in part omitted or abstracted therefrom.

This also causes your product to be misbranded under Section 403(a)(1) of the Act because the product labeling is false and misleading in that Selenium has been in part omitted.

We request that you notify this office in writing within 15 working days of receipt of this letter stating the actions you will take to correct the violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Failure to make prompt corrections may result in further enforcement action being initiated by the FDA. This could include seizure of illegal products and injunction against the manufacturer and/or distributor of illegal products.

This letter does not represent a comprehensive review of all of the products distributed by your firm, nor does it represent a complete review of all product labeling, which may include product brochures, product catalogs, newsletters and Internet web sites, as applicable. As owner, it is your responsibility to ensure that all products distributed by your firm are in compliance with the Act and its implementing regulations.

Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated in the letterhead. Ms. Wisecup may be reached at (612) 334-4100 ext. 124.

Sincerely,

Annette Byrne
Acting Director
Minneapolis District

TSW/ccl